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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,449

03/28/2005

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4007561-173520

8257

23570 7590 09/21/2010
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EXAMINER

TOSCANO, ALICIA

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

09/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,449

Applicant(s)

YAMANE ET AL.

Examiner

ALICIA TOSCANO

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 26, 28, 32 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 26, 28 and 32, 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Second Declaration under 1.132

1. Applicant's second declaration under 1.132 is not persuasive. The declaration merely continues the positions previously argued by Applicant in the previous responses. The declaration sets forth that Matsumoto teaches endcapping and endcapping does not significantly increase the MW of the polymer. The declaration sets forth that the temperature and reaction time of the claims are not met by Matsumoto and that one of ordinary skill would recognize that in the twin screw extruder used by Matsumoto, the degree of kneading is so high that a short process time would typically be required. The declaration sets forth that the endcapping reaction would preferentially take place in a twin screw extruder because of the high degree of kneading, whereas the present application is conducted at lower temperatures. Because of the lower temperatures and because the reaction is conducted for 10-30 minutes, chain lengthening occurs. Applicant argues Kureha is the first and only company to produce large volumes of PGA.
2. The Examiner disagrees. Applicant's statements as to time and temperature resulting in chain lengthening in the instant application and end capping in Matsumoto are merely speculative. Applicant offers no experimental data to back up their speculation. The method of Matsumoto and Applicant are very nearly identical. The temperatures are very nearly identical. It would be unrealistic for one to react a polymer composition in a short, instantaneous, or, 2-3 minute, timeframe because one needs complete mixing and one desires the complete reaction of the products. Applicant

offers no evidence that one can end cap a polymer melt in only a few seconds time. Applicant's method is as low as 10 minutes of mixing. It is not unrealistic to believe that Matsumoto mixes for 10 minutes. Regarding the temperature, once a polymer is melted, it is melted. Applicant has given no experimental data to support the speculation that a lower reaction temperature yields a chain extending result whereas a high reaction temperature yields end capping. Regarding the opening of a plant to produce large volumes of PGA: the opening of a plant is not a measure of non-obviousness. Maybe a plant had not been opened sooner because there was not enough demand for PGA. Applicant has not successfully shown any measure of long felt need or commercial success. As such Applicant's arguments are not persuasive and the rejection stands as set forth below.

3. Additionally, the Examiner notes that the second reference (Bonsignore) uses the same reaction (oxazoline and PGA) to chain lengthen the polymer. Even if evidence of a difference in 10 minutes or 30 degrees of temperature were shown, Bonsignore discloses the desire to chain lengthen using oxazoline. It is unclear how such evidence would be sufficient to overcome such a rejection.

4. Applicant has continued to put forth the same arguments since prosecution began in 2/2/07. The Examiner reminds Applicant of their right to appeal the decision of the Examiner. Without experimental data to the contrary, the Examiner will continue the positions previously set forth.

Claim Objections

5. Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The requirements of claim 26 have been amended into claim 11, thusly it fails to further limit the parent claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 11, 26 and 28, 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto.

Elements of this rejection are as set forth in the action dated 11/19/09 reiterated below in its entirety.

Matsumoto discloses aliphatic polyesters. Said polyesters are the reaction product of polylactic acid and an oxazoline (abstract). The polylactic acid may be produced from the ring opening polymerization of a cyclic dimer [0010]. Polyglycolic acid may be used [0009]. The oxazoline compound may be 2,2'-diphenylene bis(2-oxazoline) [0014], [0021] and examples. The oxazoline is reacted at a temperature of around 220C [0036]. The molecular weight of the polylactic acid, before reaction with oxazoline, is from 50,000 to 300,000 [0010]. When polyglycolic acid is used it is the Examiner's position that one would use the same MW as taught for use for the

polylactic acid, since Matsumoto teaches the polymers as functional equivalents.

Matsumoto discloses the use of the oxazoline to terminate the carboxyl end groups of the polylactic acid, however, it is the Examiners position that use of the bis(2-oxazoline) inherently crosslinks, or chain extends, via reaction between two neighboring polylactic acid end groups since this is the same reaction composition and method used by Applicant. Since the oxazoline will inherently bond two ends of neighboring polylactic acid chains the Examiner finds the increase in molecular weight to be inherent in the reaction of Matsumoto. Regarding range "3 to 10 parts by weight" of the chain-lengthening reactant, Matsumoto discloses the desire to have a content of unreacted terminal blocking agent of 5 wt% or less in the molded article [0021]. In order to have 5 wt% remaining after reaction, the composition would have to include at least that much during reaction, thusly a prima facie case of obviousness exists over the range. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.

Since the composition requirements are met it is the Examiners position that a MW ratio of at least 1.35, the property requirements of T2-T1, a PDI of 1.9 and an end MW of 120,000-500,000 would be inherent in the composition. If there is any difference between the above composition and the composition of the instant claims the difference would have been minor and obvious. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are

inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP 2112.01(I) , *In re Best*, 562 F2d at 1255, 195 USPQ at 433, *Titanium Metals Corp v Banner*, 778 F2d 775, 227 USPQ 773 (Fed Cir 1985), *In re Ludtke*, 441 F2d 660, 169 USPQ 563 (CCPA 1971) and *Northam Warren Corp v D F Newfield Co*, 7 F Supp 773, 22 USPQ 313 (EDNY 1934).

Matsumoto does not disclose a reaction time of between 10 and 30 minutes, as required by Claim 11. Generally, the higher the reaction temperature the shorter the reaction time, however it is unclear to the Examiner what a reasonable reaction time would be. The reaction would not be instantaneous and residence times within the 10-30 minutes claimed by Applicant's would not be unrealistic in order to ensure complete mixing and complete reactions. As such a prima facie case of obviousness exists for the claimed range.

Regarding the temperature limitation of not lower than the melting temperature but no higher than 240C: Matsumoto exemplifies the use of PLA (polylactic acid) and PGA (polyglycolic acid). Matsumoto discloses a reaction temperature of 220C when using PLA and 270C when using PGA. The melting point of PGA is 224C and the melting point of PLA is 176C. As such Matsumoto is using a reaction temperature, in both instances, of about 45 degrees higher than the melting point, which does not anticipate the claimed temperature range. However, since the polymers are in the melted state it is the Examiner's position that the degree of heating above melting point does not affect the polymers reactivity (i.e. one could pick any temperature within

reason above the melting temperature but below that which the polymer would degrade or burn), and the chosen temperature above the melting point is a result effective variable, increasing the temperature decreases the melt viscosity, and vice versa. Further, the reaction between the oxazoline and polymer would also be affected by the temperature, wherein a faster reaction time would be expected as one increases the temperature, and vice versa.

As such the Examiner finds that a prima facie case of obviousness exists to optimize the temperature depending on the viscosity and reaction time desired, meeting the temperature requirements of the claims.

Remarks:

Applicant argues it is generally difficult to obtain high molecular weight PGA. Applicant argues Matsumoto chain lengthens his composition. Applicant argues end capping of Matsumoto occurs after polymerization of the polymer. Applicant argues there is no teaching of the 3-10 parts by weight oxazoline to polymer. Applicant argues the temperature requirements are not met. Applicant argues one of ordinary skill would recognize that the extruder used in Matsumoto would require only a short reaction time. Applicant argues the temperature affects the mobility of PGA and at high temperatures endcapping would preferentially take place. Applicant argues chain extending would occur in the melt kneading of Applicant's claims. Applicant argues the MW of Matsumoto is drawn to PLA, not PGA. Applicant argues no motivation to optimize has been put forth.

The Examiner disagrees. Both Applicant and Matsumoto are melt kneading their polymers. That Matsumoto is in an extruder and "high shear" is used is thusly moot since this is the same mechanism used by Applicant. If it is so hard to obtain high molecular weight PGA it is unclear to the Examiner why Applicant cannot supply experimental data showing that Matsumoto merely chain lengthens. Applicant admits the two processes are very similar and speculates that the "big" differences of 10 minutes in time (assuming instantaneous reaction, as Applicant is eluding to) and 30 degrees in temperature result in the chain lengthening versus end capping. It is unclear why Applicant cannot run a few experiments to give weight to the speculation put forth. Applicant has continued these arguments throughout the entire prosecution. The Examiner has consistently put forth the position that Matsumoto discloses a strikingly similar composition and reaction. Applicant's arguments that a few minutes make the difference between chain extending and end capping are not persuasive since these few minutes are within what one of ordinary skill would deem necessary for complete mixing and reaction to occur. A reaction between an end capping agent and a polymer are not instantaneous because sufficient mixing is needed so that the end capping agent (which is much smaller than a polymer) can find the endgroups of a polymer chain. Applicant's speculation is thusly not persuasive. Arguments regarding the amount of oxazoline are not persuasive since Matsumoto must use at least 5 wt% otherwise less than 5 wt% could not remain after reaction. Positions based on the temperature and time are as set forth above. The Examiner has put forth proper reasoning when making the obviousness rejections. The Examiner has not merely

stated that "it is obvious to try". It is obvious to try any melting temperature above the melting point since this would not generally affect the reaction rate. It is obvious to react for sufficient amounts of time so that the polymer and reactive agent are properly mixed and can react with each other. This does not occur instantaneously and Applicant offers no evidence that such would not result in the claimed end product. That the MW in the description of Matsumoto is drawn to PLA is moot, one looking to use PGA would use the same MW range. It is unclear to the Examiner what other MW one would immediately envisage using and the Examiner requests evidence to the contrary. As such Applicant's arguments are not persuasive and the rejection stands as set forth above.

7. Claims 11, 26 and 28, 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonsignore in view of Matsumoto.

Elements of this rejection is as set forth in the action dated 6/2/08 reiterated below in its entirety. Applicant has deleted "copolymer" from the claims. Bonsignore discloses copolymers of PLA and PGA. As currently written, "a polymer of glycolide" includes any polymer or copolymer thereof. Thusly the PLA-co-PGA still meets the requirements of the claims. The rejection has been clarified in the entire rejection below. See remarks below.

Bonsignore discloses the production of high molecular weight polylactic acid co polyglycolic acid. Bonsignore discloses that since relatively small amounts of polylactic

acid are used in industry it is very expensive to obtain large MW polylactic acid with high purity and discloses reacting the carboxyl end groups of the polylactic acid with bis-oxazoline (abstract) is a way to obtain the desired purity and MW less expensively (Column 2 lines 14-19). The polylactic acid-co-polyglycolic acid may be produced by the ring opening polymerization of dilactones (Column 3 Lines 62-65). As currently written, a "polymer of glycolide" includes any polymer or copolymer thereof. The molecular weight of the polymer before the reaction is 2,000-15,000 (Column 1 Line 17). The molecular weight after reaction with a bis-oxazoline is 50,000-100,000 (Column 6 Lines 26-28).

Bonsignore does not disclose the use of an end MW of greater than 181K or the use of at least 30,000 MW PGA as a starting material as required by Claim 11.

Matsumoto includes elements as set forth above. Matsumoto discloses the use of a polylactic acid of MW between 50k and 400k because when the MW is within this range the physical properties, such as strength, are excelled [0010].

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Bonsignore the use of a MW of 50,000 to 400,000 as the final MW, as taught by Matsumoto, in order to create articles with superior physical properties.

The start range of "at least 30,000" and the end range of 120,000 lies within this range.

The polydispersity of polymer compositions is high unless specific conditions are met to yield a low PDI. Since the reaction conditions of the polymer has been met the

Examiner finds the PDI of at least 1.9 to be inherent in the composition of Bonsignore. As the composition requirements have been met the Examiner finds the properties of the claims to be inherent.

If there is any difference between the above composition and the composition of the instant claims the difference would have been minor and obvious. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP 2112.01(I) , *In re Best*, 562 F2d at 1255, 195 USPQ at 433, *Titanium Metals Corp v Banner*, 778 F2d 775, 227 USPQ 773 (Fed Cir 1985), *In re Ludtke*, 441 F2d 660, 169 USPQ 563 (CCPA 1971) and *Northam Warren Corp v D F Newfield Co*, 7 F Supp 773, 22 USPQ 313 (EDNY 1934).

Bonsignore does not include the use of a specific bis-oxazoline nor the amount of bis-oxazoline useful to create high molecular weight polylactic acid.

Matsumoto discloses the use of 0.5-2 wt% 2,2'-m-phenylene bis(2-oxazoline) [0021], Examples, Table 1. 2,2'-m-phenylene bis(2-oxazoline) is preferred because of its stability with the polyester resin [0021], and the amount used is preferred so as to minimize the amount of unreacted bis-oxazoline in the composition [0021]. The amount should be minimized so as to have less than 5 wt% of unreacted oxazoline in the end product in order to obtain good end molding properties [0021]. As set forth in the action dated 4/22/10, in order to have 5 wt% remaining after reaction, the composition would have to include at least that much during reaction.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Bonsignore the use of at least 5 wt% oxazoline, as taught by Matsumoto, since this amount of said species is taught to have superior stability in the resin and this would thusly lead to a superior end product.

Bonsignore does not disclose the reaction time. The time of reaction will dictate the crosslink density and thus the molecular weight of the polylactic-co-oxazoline product. The molecular weight of the polylactic acid dictates the overall properties of the resin. Higher molecular weight will yield better strength and mechanical properties than low molecular weight polymer however too high of a molecular weight will lead to difficulties with molding.

It would have been obvious to one of ordinary skill in the art at the time of the invention to tailor the reaction time of Bonsignore in order to achieve the desired crosslink density, or molecular weight, of the polylactic acid in order to create articles with superior molding properties.

Generally, the higher the reaction temperature the shorter the reaction time, however it is unclear to the Examiner what a reasonable reaction time would be. The reaction would not be instantaneous and residence times within the 10-30 minutes claimed by Applicant's would not be unrealistic. As such a prima facie case of obviousness exists for the claimed range.

As the compositional requirements are met the Examiner finds the MW increase and further properties such as PDI, T2-T1 difference and weight loss starting temperature required by the Claims to be inherent.

Regarding the temperature limitation of not lower than the melting temperature but no higher than 240C of claim 11 and its dependants: Bonsignore discloses that either polylactic acid or polyglycolic acid may be used. Bonsignore recognizes that PLA has a melting point of about 175 whereas PGA has a melting point of about 230 (Column 4 lines 26-34). Bonsignore discloses solution polymerization in the Examples, Bonsignore does not disclose melt polymerization.

Matsumoto includes elements as set forth above. Matsumoto discloses melt polymerization as a suitable reaction process for the same reaction taught in Bonsignore.

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945), a prima facie case of obviousness exists to use the process of Matsumoto to react the polymers of Bonsignore, since the process is taught to be suitable for such. Since the polymers in Matsumoto are in the melted state it is the Examiner's position that the degree of heating above melting point does not affect the polymers reactivity (i.e. one could pick any temperature within reason above the melting temperature but below that which the polymer would degrade or burn), and the chosen temperature above the melting point is a result effective variable, increasing the temperature decreases the melt viscosity, and vice versa. Further, the reaction would also be affected by the temperature, wherein a faster reaction time would be expected as one increases the temperature, and vice versa.

As such the Examiner finds that a prima facie case of obviousness exists to optimize the temperature depending on the viscosity and reaction time desired, meeting the temperature requirements of the claims.

Remarks:

Applicant argues Bonsignore does not disclose PGA or the MW of the claims. Applicant argues there is no apparent reasoning to apply the teachings of Bonsignore to glycolic acid. Applicant argues the method requirements are not taught in Bonsignore and his Examples are not within that of the claims. Applicant argues Bonsignore reacts at temperatures lower than the melting point in the examples. Applicant argues the temperature positions of the Examiner are not supported and Matsumoto does not teach it to be a result effective variable. Applicant argues Matsumoto teaches endcapping and one would not look to such for the reaction of Bonsignore. Applicant argues Matsumoto does not meet the method requirements of the claims.

The Examiner disagrees. Bonsignore discloses copolymers of PLA and PGA, the claims are open to such a limitation since "polymer of glycolide" includes any polymer or copolymer thereof. That the methods are not taught in Bonsignore are moot, one looking to react oxazoline compounds with PLA-co-PGA would find Matsumoto pertinent to the problem at hand. That the Examples of Bonsignore do not disclose the melting temperature requirements are moot since the reaction therein is not an example of using oxazoline compounds. Applicant argues that the temperature positions are unsupported are not found persuasive. It is generally known by one of ordinary skill that

as you heat up a polymer the viscosity therein decreases. It is also generally known that by increasing temperature a reactive moiety (such as the oxazoline) reacts faster. As such that Matsumoto does not teach these concepts or these elements to be result effective variables is found moot. As set forth above, one looking to react oxazoline with PGA or PLA would find Matsumoto pertinent to the reaction at hand, thusly that Matsumoto teaches endcapping whereas Bonsignore is chain lengthening is not found persuasive. Matsumoto meets the method requirements of the claims as set forth above. As such Applicant's arguments are not found persuasive and the rejection stands as set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is (571)272-2451. The examiner can normally be reached on M-F 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT

/RANDY GULAKOWSKI/

Supervisory Patent Examiner, Art Unit 1796